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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	NANO:002USD1	5127

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,320	Applicant(s) MUMPER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-57 is/are pending in the application.
- 4a) Of the above claim(s) 48-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-47, 51, 56 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/31/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2008 has been entered.

The indicated allowability of claims 33-57 is withdrawn in view of the newly discovered reference(s) to Suzuki et al. and Rajaiah et al. Rejections based on the newly cited reference(s) follow. Furthermore a newly discovered 112 2nd rejection was found and made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically within the claim it is not clear what type of polymer "polyvinyl" is referring to, for instance polyvinyl can refer to vinyl ethers, polyvinyl chloride, polyvinyl acetate, polyvinyl alcohol etc. Further clarification is required within the claim.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-34,42-45 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 4,715,369, cited by applicant).

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Suzuki discloses a method for treating an injury on the oral mucosa by applying a covering material comprising an adhesive composition and a non-adhesive layer made from constituents such as bees wax. See abstract, col 2 lin 14-22, col 5 lin 44-col 6 lin 3. The adhesives within the examples were very thin (thickness from 0.86 to 1.33 mm) and lower than applicants claimed lower limit for the thickness of their claimed film. However the examples with the above thicknesses did not use a non-adhesive layer even though other examples (Ex 3) did employ a non-adhesive layer, the thickness of Ex 3 however was not disclosed. Suzuki did suggest that a preparation containing two layers (adhesive and non-adhesive) mutually reinforce each other, thus the adhesive layer can be even thinner. Suzuki also disclosed that thin films advantageously alleviates the feeling of touchy discomfort and makes itself applicable to flexure. Thus from the disclosure within Suzuki it would be obvious to one of ordinary skill in the art that the two layer film could be as thin as the adhesives disclosed within example 1 that did not employ a non-adhesive layer since the two layers reinforce each other they could be very thin and retain the requisite material feel and flexibility. Furthermore it is noted by the examiner that the amount of adhesive and non-adhesive used in example 3 was 60 mg combined (40 mg of adhesive and 20 mg of non-adhesive), while in example 1 the amount of adhesive used to form the films was around 90 mg. It is further noted by the examiner that example 3 and example 1 both had the same diameter. Thus it is quite reasonable to assume that since the total amount of adhesive and non-adhesive from example 3 is smaller in amount than just the adhesive from example 1 the dimensions for the thickness would also be smaller; the thickest disk

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from example 1 was 1.33 mm. Regarding the limitation of claim 34, 40 mg of adhesive and 20 mg of non-adhesive were used in example 3, thus the wt percent of adhesive used was around 66% and the amount of non-adhesive was around 33%, these wt percents are within applicants claimed range. Regarding claims 42 and 45, Suzuki specifically discloses that the non-adhesive layer could comprise a mixture of constituents that included bees wax and PEG. Regarding claim 44, it is considered by the examiner to be simple optimization of parameters to vary the amounts of ingredients within the non-adhesive layer in order to obtain the desired characteristics (flexibility, water solubility etc) for that non-adhesive layer. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of polymer within the non-adhesive layer would have been obvious at the time of Applicant's invention. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Regarding claim 57 it is obvious that since

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the disclosure of Suzuki is obviously within the scope of applicants claimed invention any property of the wax film will also necessarily be met since it is obvious that the same composition and/or material will have the same properties including its adhesive properties.

Claims 33-47 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 4,715,369) in view of Biegajski et al. (5,700,478, cited previously).

Suzuki is disclosed above. Suzuki does not disclose the specific water insoluble mucoadhesive polymers within dependent claims 36-37 nor does Suzuki disclose the use of the specific film formers as required in dependent claims 35 and 41 and lastly Suzuki is silent on the use of a pharmaceutical compound as required in dependent claim 47.

Biegajski discloses double layered, mucoadhesive drug delivery device wherein the adhesive layer and the second polymer layer contain the drug to be delivered (abstract, col 35 lin 30). Biegajski is suggestive that a wax can be used as suitable layer (col 4, lin 35). Biegajski discloses the use of Eudragit polymethacrylate copolymers (col 22, lin 15) and Carbopol 934 (col 28, lin 40-45) for making the adhesive layer for the drug delivery device and the wt% of polymer components (col 8, lin 50). Carbopol polymers are polymers of acrylic acid cross-linked with polyalkenyl ethers or divinyl glycol. Biegajski discloses a wax-film composite wherein the mucoadhesive layer is a

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copolymer of methacrylic acid esters with diethylaminoethyl methacrylate (col 33, lin 55-60).

One of ordinary skill in the art would have a reasonable expectation of success in combining the references above because both are related to the same filed of endeavor, mucoadhesives for placement within a mucosa-lined body part. Thus the claimed invention would have been *prima facie* obvious because the substitution of one known element such as the mucoadhesive layer disclosed within Biegajski for another known element such as the mucosadhesive layer disclosed within Suzuki would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 33-47,51 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah et al. (US 6,677,391 B1, cited by applicants) in view of Suzuki et al. (US 4,715,369) in view of Biegajski et al. (5,700,478).

Rajaiah discloses denture adhesives which contains an adhesive composition including mucoadhesive polymers such as carbopol and non-aqueous denture adhesive carriers including microcrystalline wax that could be a self supporting layer characterized by its ability to maintain strength and provide integrity for the adhesive composition in the presence of water and/or saliva. See abstract, col 3 lin 21-50, col 8 lin 35-48 and claims 1-3,10,12. The denture adhesives could also be used as a bioadhesive that comprise one or more therapeutic agents that could be selected from numerous actives including insulin (satisfies limitation that active is a protein). See col 9 lin 58-col 10 lin 10.

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Rajaiah does not recite the use of the specific film formers as required in dependent claims 35 and 41, nor does Rajaiah disclose the thickness of the adhesives.

Suzuki is disclosed above. Suzuki disclosed that there was a well known and felt need in the art to provide thin preparations of bioadhesives in order to alleviate the feeling of touchy discomfort and further to make the preparation applicable to flexure. See col 5 lin. Thus there was a known art problem in that adhesives have the undesirable characteristic of making the patient in need feel discomfort and the solution to this problem as disclosed within Suzuki was to produce a thin adhesive. One of ordinary skill in the art would have been motivated and had a reasonable expectation of success in producing thin bioadhesive preparations such as those disclosed within Rajaiah in order to alleviate the feeling of touchy discomfort and further to make the preparation applicable to flexure as described by Suzuki.

Biegajski is disclosed above. Biegajski is used only for the disclosure within that Eudragit polymers were well known to be used within mucoadhesive preparations. One of ordinary skill in the art would have a reasonable expectation of success in combining the references above because they are all related to the same general field of endeavor, bioadhesives for placement within a mucosa-lined body part. Thus the claimed invention would have been *prima facie* obvious because the addition of one known element such as the Eudragit polymers contained within the mucoadhesive layer as disclosed within Biegajski and combine it with the mucosadhesive layer disclosed within Suzuki would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is generally considered to be prime facie obvious to combine

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compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of bioadhesives. It therefore follows that the instant claims define prime facie obvious subject matter.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618